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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,017	04/17/2001	Elisabeth Lacy Belden	P-9312	6994
27581	7590	09/21/2005	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			BUNIN, ANDREW M	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TAK

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/836,017	BELDEN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Andrew M. Bунин	3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 June 2005.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 46-49,51 and 54-89 is/are pending in the application.
  - 4a) Of the above claim(s) 46-49,51 and 54-79 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 80-89 is/are rejected.
- 7) Claim(s) 80 and 89 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 17 April 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____.

## DETAILED ACTION

### ***Claim Objections***

Claims 80 and 89 are objected to because of the following informalities: It has not been clearly established as to how the deflection wire is connected to the distal end of the distal portion of the guidewire or stylet in the claim.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 80-89 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg (US 6315789) in view of Hammerslag et al. (US 5308324). Cragg discloses a system fully capable of placing an electrical lead having an electrode assembly in a patient (column 7, lines 20-30), the system comprising: a guide wire 54 or stylet including a proximal portion and a distal portion, an electrode retention member (via 22, 34, etc.) fully capable of being adapted to temporarily couple the electrode assembly to the guide wire 54 or stylet, the proximal portion 30 extending proximal to the electrode retention member (such as 22, 34) and the atumatic distal portion 32 extending distal to the electrode retention member, and an elongate introducer (such as 18) including a lumen having a diameter sufficient to receive the proximal portion of the guide wire 54

or the stylet. In addition, Cragg discloses an inner liner 70/74 that may function as a deflection wire coupled to a distal portion of the guide wire 54. Based on the applicant's specification, the guide wire could also be designated as 18 and the deflection wire as 70/72. Hammerslag et al. also teaches a deflection wire 28 coupled to a distal end of the distal portion of the guide wire 10 (see Figures). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to include a coupled connection between a deflection wire and guide wire for this type of system as taught by Cragg and Hammerslag to create a well balanced steering system.

As for claim 81, Cragg discloses that as applied to claim 80 as well as a delivery device that is steerable. Applicant has not recited structure that would establish steerability that would define over that disclosed by Cragg.

Regarding claim 82, Cragg also discloses that as applied to claim 80 as well as an atraumatic distal portion is that is shapeable. The scope of this claim is broad and it has not been established when in the manufacturing process that the device is shapeable. The claim does not require the tip to be bendable during use. Thus the device is shapeable and is fully capable of being shaped.

Regarding claim 83, Cragg discloses that as applied to claim 80 as well as an electrode retention member (22, 34) that has an outer surface adapted to form a press fit with an inner surface of a tubular portion of the electrode assembly to temporarily couple the electrode assembly to the guide wire 18 as shown in Figure 8.

Regarding claim 84, Cragg discloses that as applied to claim 80 as well as an electrode retention member that is a polymeric plug (column 10, lines 40-60). Cragg

discloses the use of polymers, and it can be broadly and reasonably interpreted to be a "plug."

Regarding claim 85, Cragg discloses that as applied to claim 80 as well as an electrode retention retention member that is fully capable of rotation when mounted upon the delivery system.

Regarding claim 86, electrode assembly that would necessarily include an elongate lead extending proximally therefrom, and a diameter of the introducer lumen that is sufficient to slidably engage the lead (column 7).

Regarding claim 87, Cragg discloses a system as recited in claim 87, but does not explicitly recite a distal tip of the introducer that includes a nesting taper to aid in alignment of the electrode assembly for dislodging the electrode assembly. However, the tip of Cragg can be considered an equivalent since the function of dislodging the electrode is equally performed. Therefore, it would have been obvious, if not inherent, to substitute one type of tip for another.

Regarding claim 88, Cragg discloses that as applied to claim 80 as well as a distal tip of the introducer that is radiopaque (column 10, lines 40-60).

#### ***Response to Arguments***

Applicant's arguments filed June 28, 2005 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies

(i.e., deflection wire connection to guide wire) are not recited in the rejected claim(s). Applicant hasn't clearly claimed the specifics of how the guide wire connects with the deflection wire as well as any other specific features in relation to these two wires that provides a new result or unexpectedly solves any new problem in the art over the prior art. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 6671560, US 6408213, US 6192280, US 6456889, and US 5593433

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Bunin whose telephone number is (571)272-4801. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571)272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*AMB*

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9/16/05

*[Handwritten signature]*  
Henry Bennett  
Supervisory Patent Examiner  
Group 3700